

CLAIMS:

1. A pharmaceutical composition for parenteral administration comprising a therapeutically effective amount of coagulation factor VIII (FVIII) and substantially neutral colloidal particles, said particles comprising approximately 1-20 mole percent of an amphipathic lipid derivatized with a biocompatible hydrophilic polymer, said polymer carrying substantially no net charge,
- wherein said FVIII is not encapsulated in said colloidal particles.
- 10 2. The pharmaceutical composition of Claim 1 wherein the colloidal particle has a mean particle diameter of between about 0.05 to about 0.4 microns.
- 15 3. The pharmaceutical composition of Claim 2 wherein the colloidal particle has a mean particle diameter of approximately 0.1 microns.
- 15 4. The pharmaceutical composition of Claim 1 wherein said amphipathic lipid is a phospholipid from natural or synthetic sources.
5. The pharmaceutical composition of Claim 4 wherein said amphipathic lipid is egg-phosphatidylcholine.
- 20 6. The pharmaceutical composition of Claim 1 wherein said biocompatible hydrophilic polymer is selected from the group consisting of polyalkylether, polylactic and polyglycolic acid families.
7. The pharmaceutical composition of Claim 6 wherein said biocompatible hydrophilic polymer is polyethylene glycol.
- 25 8. The pharmaceutical composition of Claim 7 wherein the polyethylene glycol has a molecular weight of between about 1000 to about 5000 daltons.
9. The pharmaceutical composition of Claim 8 wherein the polyethylene glycol has a molecular weight of approximately 2000 daltons.

10. The pharmaceutical composition of Claim 1 wherein the FVIII is from a natural source.
11. The pharmaceutical composition of Claim 1 wherein the FVIII is recombinantly prepared.
- 5 12. The pharmaceutical composition of Claim 1 wherein the particle to FVIII ratio (w/unit FVIII) is between about 0.1 mg/unit and about 10 mg/unit.
13. The pharmaceutical composition of Claim 12 wherein the particle to FVIII ratio (w/unit FVIII) is approximately 1 mg/unit.
- 10 14. Method of treatment of a patient suffering from hemophilia comprising administrating to said patient a pharmaceutical composition for parenteral administration comprising a therapeutically effective amount of coagulation factor VIII (FVIII) and substantially neutral colloidal particles, said particles comprising approximately 1-20 mole percent of an amphipathic 15 lipid derivatized with a biocompatible hydrophilic polymer, said polymer carrying substantially no net charge,
- wherein said FVIII is not encapsulated in said colloidal particles.
15. A method according to Claim 14 wherein said patient has 20 developed FVIII inhibitor antibodies.
16. Use of a colloidal particle in the preparation of a pharmaceutical composition for parenteral administration for treatment of a patient suffering from hemophilia comprising a therapeutically effective amount of coagulation factor VIII (FVIII) and substantially neutral colloidal particles, said particles comprising approximately 1-20 mole percent of an amphipathic lipid derivatized with a biocompatible hydrophilic polymer, said polymer carrying substantially no net charge,
- wherein said FVIII is not encapsulated in said colloidal particles.

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17. A use according to ~~Claim 18~~¹⁶ wherein said patient has developed FVIII inhibitor antibodies.

18. A pharmaceutical composition for parenteral administration comprising a therapeutically effective amount of a protein or polypeptide and substantially neutral colloidal particles, said particles comprising approximately 1-20 mole percent of an amphipathic lipid derivatized with a biocompatible hydrophilic polymer, said polymer carrying substantially no net charge,

wherein said protein or polypeptide is selected from the group consisting of:

(a) proteins or polypeptides capable of externally binding said colloidal particles; and

(b) proteins or polypeptides capable of binding polyethylene glycol, and wherein said protein or polypeptide is not encapsulated in

said colloidal particles.

19. Use of a colloidal particle in the preparation of a pharmaceutical composition for parenteral administration comprising a therapeutically effective amount of a protein or polypeptide and substantially neutral colloidal particles, said particles comprising approximately 1-20 mole percent of an amphipathic lipid derivatized with a biocompatible hydrophilic polymer, said polymer carrying substantially no net charge,

wherein said protein or polypeptide is selected from the group consisting of:

(a) proteins or polypeptides capable of externally binding said colloidal particles; and

(b) proteins or polypeptides capable of binding polyethylene glycol, and wherein said protein or polypeptide is not encapsulated in said colloidal particles.